

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE**

NIPPON SHINYAKU CO., LTD., a)
Japanese company;)
Plaintiff,) CIVIL ACTION NO. 1:21-CV-01015-LPS
v.)
SAREPTA THERAPEUTICS, INC., a)
Delaware corporation)
Defendant.)
)

Public Version Filed September 1, 2021

**NIPPON SHINYAKU'S REPLY BRIEF IN
SUPPORT OF ITS MOTION FOR PRELIMINARY INJUNCTION**

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I. INTRODUCTION

The [REDACTED]

[REDACTED]

[REDACTED].¹ Sarepta elected not to [REDACTED]

[REDACTED]

Despite [REDACTED], Sarepta filed its seven IPR Petitions before the PTAB [REDACTED]. Sarepta now asks this Court to [REDACTED] and exclude the IPR Petitions from [REDACTED]. Nothing in the [REDACTED] or otherwise, justifies redefining or narrowing [REDACTED]. To do so, would violate the “cardinal rule . . . that, where possible, a court should give effect to *all* contract provisions.” *Martin Marietta Materials, Inc. v. Vulcan Materials Co.*, 68 A.3d 1208, 1221 (Del. 2012) (citations omitted).

Sarepta’s [REDACTED] also irreparably harmed Nippon Shinyaku by depriving it of its [REDACTED] for patent validity challenges. That Sarepta [REDACTED] away its right to file IPR petitions is not a basis [REDACTED] in a manner contrary to [REDACTED] nor should it tip the balance of equities in Sarepta’s favor. Nor can Sarepta invoke the public policy favoring post-grant challenges to patents to overcome the parties’ [REDACTED] and tip the public interest in Sarepta’s favor. The public interest is served by [REDACTED]

[REDACTED], not ignoring express provisions in a [REDACTED]

[REDACTED]

¹ Capitalized Terms not otherwise defined herein have the same meaning as set forth in Nippon Shinyaku’s Memorandum in Support of Its Motion for Preliminary Injunction. See D.I. 5.

II. NIPPON SHINYAKU IS ENTITLED TO A PRELIMINARY INJUNCTION

A. Nippon Shinyaku is Likely to Show that Sarepta's Filing of the IPR Petitions

The plain language of the MCA is clear and unambiguous. [REDACTED]

[REDACTED].² Sarepta neither disputes that the [REDACTED] nor disputes that the filing of its IPR Petitions [REDACTED]. Instead, Sarepta asks this Court to [REDACTED] in a manner contrary to this [REDACTED] and that effectively nullifies portions of the [REDACTED].

1.

Sarepta's argument that [REDACTED] is contrary to the [REDACTED] D.I. 18 at 11. The parties [REDACTED]

[REDACTED]
3

Sarepta's IPR Petitions [REDACTED]; they are disputes concerning seven NS patents brought before an administrative agency: the PTAB. [REDACTED]

² D.I. 2-1 at 6-7, [REDACTED]

³ *Id.* at 2 (emphasis added).

[REDACTED] . Sarepta [REDACTED]
[REDACTED] when it filed patent challenges before the PTAB instead of in this District.

Sarepta’s arguments that [REDACTED]

[REDACTED] are unavailing. Sarepta first focuses on [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED],”

it can only be applied to district court actions. D.I. 18 at 3, 11-12. That [REDACTED] also parallels Article III or describes a federal court’s jurisdiction is irrelevant, as [REDACTED] equally applies to IPR proceedings. IPR petitions “aris[e] under U.S. law,” as 35 U.S.C. § 311 codifies the IPR statute, and relate to patent invalidity, as IPR petitions present invalidity grounds under 35 U.S.C. § 102 and/or § 103.⁴ See 35 U.S.C. § 311. Sarepta concedes as much. D.I. 18 at 12.

Sarepta’s additional arguments that [REDACTED]

[REDACTED]
[REDACTED] also fail to support its attempt to exclude IPR proceedings [REDACTED]. *Id.* at 12-13. There is nothing ambiguous or contradictory in [REDACTED]
[REDACTED]
[REDACTED]

⁴ To the extent Sarepta argues that IPR petitions seek to cancel patent claims as unpatentable and therefore are not “[REDACTED],” its argument contradicts its position regarding [REDACTED] [REDACTED] Sarepta does not dispute that [REDACTED] . D.I. 18 at 10.

Moreover, the lack of an [REDACTED]
[REDACTED] and the inclusion of [REDACTED]
[REDACTED] does not necessitate a [REDACTED]
than [REDACTED]. In *Dodocase VR, Inc. v. MerchSource, LLC*, for example, the parties entered into an agreement that included a no-challenge clause and a forum selection clause. The no-challenge clause stated that “MerchSource shall not . . . attempt to challenge the validity or enforceability of the Licensed IP” while the forum selection clause stated that “***subject matter and personal jurisdiction*** are proper in courts located in San Francisco County or Orange County, California and that disputes shall be litigated before” these courts. 767 Fed. App’x 930, 932 (Fed. Cir. 2019). Despite the lack of an express reference to IPR proceedings in either the no-challenge clause or forum selection clause, and the forum selection clause’s inclusion of language specific to district court, the Federal Circuit held that the forum selection clause extended to PTAB proceedings. *Id.* at 934-935.

Here, both Sarepta and Nippon Shinyaku [REDACTED]
[REDACTED]

Sarepta could have [REDACTED]. It did not.

2. **Nippon Shinyaku’s [REDACTED]**

Sarepta’s argument that Nippon Shinyaku’s [REDACTED]

[REDACTED] is equally unavailing. D.I. 18 at 10. A review of the [REDACTED]

[REDACTED] shows [REDACTED]

[REDACTED]

[REDACTED]. That is, there would be [REDACTED]

[REDACTED] . D.I. 5 at 4; D.I. 18 at 10.

[REDACTED] in the District of Delaware.⁵ Thus, it is clear [REDACTED]

[REDACTED] are [REDACTED].

3. [REDACTED]

Sarepta incorrectly asserts that “[REDACTED]

[REDACTED].” D.I. 18 at 14. As discussed in Section II.A.1, Sarepta [REDACTED], which, as Sarepta does not

[REDACTED] [REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]
[REDACTED]

[REDACTED], it may still challenge the validity of the NS Patents in the District of Delaware.

Sarepta’s argument that [REDACTED]

[REDACTED]
[REDACTED] D.I. 18 at 14. Although [REDACTED]
[REDACTED], it is of no moment because [REDACTED]
[REDACTED]

⁵ D.I. 2-1 at [REDACTED]

Sarepta's additional arguments focusing on language in [REDACTED]

[REDACTED] are equally meritless. First, that [REDACTED]

[REDACTED] is irrelevant since the IPR Petitions at issue were not filed during [REDACTED] D.I. 18 at 14. Second, as Sarepta concedes, [REDACTED]

[REDACTED].” *Id.* Those included [REDACTED]

[REDACTED]. D.I. 5, Ex. 1 at 2. The parties' [REDACTED]

[REDACTED] further evidences that Nippon Shinyaku and Sarepta knew how to [REDACTED] but chose not to do so for IPR petitions. Thus, by [REDACTED]

[REDACTED], Sarepta preserved [REDACTED]

4. The Case Law Supports Nippon Shinyaku's Argument that Sarepta

In further support of [REDACTED], Sarepta relies on the Southern District of New York case *Kannuu Pty Ltd. v. Samsung Elecs. Co.*, No. 19 Civ. 4297 (ER), 2021 WL 195163 (S.D.N.Y. Jan. 19, 2021). D.I. 18 at 16. Sarepta ignores the distinctions between [REDACTED]

[REDACTED] In *Kannuu*, the confidentiality agreement implicated confidentiality, not intellectual property rights. 2021 WL 195163, at * 4. The forum selection clause merely recited that “any legal action, suit or proceeding ‘*arising out of or relating to [the] Agreement or the transactions contemplated hereby*’ must be instituted exclusively in a court of competent jurisdiction, federal or state, located within the Borough of Manhattan, City of New York, State of New York and in no other jurisdiction.’” *Id.* at *1 (emphasis added).

Because the agreement concerned confidentiality, the court determined that IPR proceedings “do not relate to the Agreement itself, as *they do not implicate any of the obligations under the Agreement,*” and IPR proceedings do not “relate to transactions contemplated under the Agreement.” *Id.* at *4-5 (emphasis added). In contrast, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].^{6,7}

These facts are consistent with those in *Dodocase* and *Nomadix, Inc. v. Guest-Tek Interactive Ent., Ltd.*, No. 2:19-cv-04980, 2020 WL 1939236 (C.D. Cal. Apr. 22, 2020). Although *Dodocase* and *Nomadix* involved a license agreement and a grant of intellectual property rights, not a confidentiality agreement, the pertinent holding in each of those cases was that a forum selection clause, [REDACTED], can apply to PTAB proceedings where the parties’ contract warrants that interpretation. 767 Fed. App’x at 934-935; 2020 WL 1939826, at *1. The distinctions that Sarepta attempts to draw are meritless.

For example, Sarepta’s attempt to distinguish the agreements at issue in the *Dodocase* and *Nomadix* cases from [REDACTED] because [REDACTED] (as opposed to a complete no-challenge clause) is irrelevant. D.I. 18 at 15. Sarepta is correct that the [REDACTED]

⁶ D.I. 2-1 at [REDACTED] (emphasis added).

⁷ Sarepta also points to *NuCurrent Inc. v. Samsung Elecs. Co.*, No. 19-cv-798 (DLC), 2019 WL 2776950 (S.D.N.Y. July 2, 2019) to support its arguments. D.I. 18 at 16. *NuCurrent* also involved an agreement that implicated confidentiality, not intellectual property rights. *Id.*, at *4. It likewise contained the same forum selection clause as in *Kannuu*. *Id.*, at *1. Thus, like *Kannuu*, the court in *NuCurrent* held that the “IPR petitions do not relate to the surviving confidentiality obligations.” *Id.*, at *4.

[REDACTED]⁸, which allowed the parties time to engage in business discussions [REDACTED].⁹ But this fact alone does not change that the parties also [REDACTED]
[REDACTED]
[REDACTED].¹⁰

Further, Sarepta's attempt to distinguish the license agreements at issue in the *Dodocase* and *Nomadix* cases from [REDACTED], D.I. 18 at 15, is also irrelevant because [REDACTED]

[REDACTED]¹¹, irrespective of [REDACTED]. Thus, there is no doubt that patent validity disputes “[REDACTED].

Accordingly, by filing its IPR Petitions before the PTAB, Sarepta [REDACTED]
[REDACTED]. Thus, Nippon Shinyaku is likely to succeed on the merits of its [REDACTED]
[REDACTED] against Sarepta. Sarepta's remaining arguments on irreparable harm (D.I. 18 at 16-17), balance of equities (*id.* at 18) and public interest (*id.* at 19-20) all rely on its faulty argument that [REDACTED]. For these additional reasons, Nippon Shinyaku's motion should be granted.

B. Nippon Shinyaku Will Suffer Irreparable Harm Absent Relief

Nippon Shinyaku will be irreparably harmed if the injunction does not issue, as it will be deprived of [REDACTED]. D.I. 5 at 7-9.¹² Sarepta's arguments

⁸ D.I. 2-1 at [REDACTED]

⁹ D.I. 18 at 6 (“discussions aimed at resolving their existing intellectual property disputes”).

¹⁰ *Id.* at [REDACTED]

¹¹ *Id.* at [REDACTED].

¹² Sarepta argues that Nippon Shinyaku's reliance on *BE & K* in its opening brief is “misplaced” because the forum selection clause conveyed “exclusive” jurisdiction on the Delaware courts and “[REDACTED].”

D.I. 18 at 17. This argument is nonsensical, as the irreparable harm derives from Nippon Shinyaku being forced to litigate in a jurisdiction other than [REDACTED]. Nothing in the case law requires the use of the term “exclusive” in said [REDACTED]. *See also Vill. Green Holding, LLC v. Holtzman*, No. CV 2018-0631-TMR, 2018 WL 4849964, at *7 (Del. Ch. Oct. 5, 2018) (collecting cases).

to the contrary again focus on its flawed reading of [REDACTED] and its assertion that [REDACTED] [REDACTED]. D.I. 18 at 16-17. For reasons discussed above, [REDACTED], and by filing the IPR Petitions, Sarepta [REDACTED].

Sarepta additionally argues that Nippon Shinyaku will not be irreparably harmed by being forced to litigate the validity of its patents on multiple fronts with the possibility of inconsistent results because Nippon Shinyaku “itself brought this alleged hardship with the filing of this action.” D.I. 18 at 17. This argument lacks merit. Nippon Shinyaku has the right to assert its patents against infringers, such as Sarepta, and it should not be punished because it [REDACTED] [REDACTED] and filed this action in the proper forum [REDACTED] [REDACTED]. Additionally, Nippon Shinyaku should not be forced to litigate the validity of its patents on multiple fronts or seek a stay of the litigation as Sarepta suggests. D.I. 18 at 18. Sarepta’s filing of its IPR Petitions [REDACTED] irreparably harms Nippon Shinyaku by depriving it of its [REDACTED].

C. The Equities Heavily Favor [REDACTED]

The balance of equities also weighs in favor of Nippon Shinyaku. As discussed above, Nippon Shinyaku would suffer irreparable harm from being deprived of its [REDACTED] and having to litigate the validity of its patents in two separate forums, or staying this proceeding, as Sarepta suggests. Sarepta’s attempt to tip the balance of equities in its favor by arguing the grant of the injunction “would preclude Sarepta from pursuing any IPR petitions *at all*, as they would be time-barred under § 315(b)” fails. D.I. 18 at 18.

Sarepta is correct that it would be time-barred from filing the IPR Petitions, but this is the [REDACTED]. See Section II.A, *supra*. Moreover, Sarepta’s assertion that an interpretation barring it from pursuing IPR challenges to the NS Patents “makes

no sense because . . . [REDACTED]

[REDACTED]

[REDACTED] ignores that Sarepta is not barred from pursuing validity challenges to the NS Patents. As Sarepta admits, it can make the *very same* invalidity arguments in defense of this case that it sought to make in its IPR Petitions. D.I. 18 at 12 (grounds raised under §§ 102 or 103). Thus, any harm to Sarepta is a matter of form over substance. While Sarepta may now prefer to challenge the NS Patents before the PTAB, it [REDACTED]

[REDACTED]

D. The Public Interest Weighs in Favor of Preliminary Relief

The public interest also weighs in favor of granting Nippon Shinyaku's preliminary injunction, as the public has an interest in [REDACTED]. D.I. 5 at 9. Even if Sarepta is correct that "strong public policies favor permitting post-grant challenges to patents that fail to meet the statutory requirements for patentability" (which the NS Patents do not), this argument ignores that "[t]here is no public interest served by excusing a party's [REDACTED]

[REDACTED] to litigate in a particular forum." *Gen. Proiecth Grp., Inc. v. Leviton Mfg. Co.*, 651 F.3d 1355, 1366 (Fed. Cir. 2011). Sarepta [REDACTED]

[REDACTED]

[REDACTED] (even if arguably more efficient) [REDACTED]

[REDACTED] There is nothing "unfair" about [REDACTED].

III. CONCLUSION

For these reasons, Nippon Shinyaku has demonstrated that it is entitled to relief, and it thus respectfully requests the Court grant its Motion for a Preliminary Injunction and order Sarepta to withdraw its IPR Petitions.

Dated: August 25, 2021

Respectfully submitted,

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